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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,937	11/26/2003	Paul J. Gerwin	132386SV/YOD GEMS:0254	9428
7590 Patrick S. Yoder FLETCHER YODER P.O. Box 692289 Houston, TX 77269-2289			EXAMINER AZARIAN, SEYED H	
			ART UNIT 2624	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/723,937

Applicant(s)

GERWIN, PAUL J.

Examiner

Seyed Azarian

Art Unit

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 12-15, 20-23 and 25-29 is/are allowed.
- 6) ☒ Claim(s) 1, 3-8 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/26/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicants' arguments filed, 9/24/2007, see page 8 through page 10, of remark, with respect to cancellation of claims 10, 11, 24 and 30, and amended claims 1, 9, 12, 16, 20, 23, 26 and 27, have been fully considered but they are moot in view of the new ground (s) of rejection as necessitated by applicant's amendment is made.

Contrary to the applicant's assertion, as he pointed out that Launay reference does not disclose "a phantom having a second portion coupled to a first portion and rotatable with respect to the first portion".

The applicant is respectfully reminded that, it is noted that the features "phantom", the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

However, Launay discloses (column 1, lines 60-67, in one embodiment of the invention, the wire is disposed helicoidally relative to the axis normal to the plane of rotation of the axis of the X-ray beam. Each wire can be disposed on a spire. Preferably, the wires have diameters that are different from one another. Each wire can be disposed at a distance from the axis normal to the plane of rotation of the axis of the X-ray beam that is different from that of the other wires. Further column 3, lines 13-17, in

order to control the performance level of a three-dimensional angiography system, it is necessary to simulate a rotating acquisition of images of the patient with a specific simulation device, also called a "phantom." The images of this phantom must be representative of the patient's blood vessels, also column 3, lines 64-67, Fig.1; the simulation device can be used in any position in space. Furthermore column 4, lines 1-22, the wires 17 through 21 are made of copper, a material with high X-ray absorption, but could also be made of another metal or alloy, as long as their diameter is adapted in accordance with the X-ray absorption of the material. The diameters of the wires are uniformly graduated, between 0.2 and 0.6 mm. The ends of the wires 17 through 21 are passed through a hole 16 and fixed with a dot of adhesive. Extending from the central shaft 14 is a cylindrical element 22 disposed on an axis 23 that is oblique relative to the axis 3. The cylindrical element 22 is connected to the central shaft 14 by a portion 24 of small diameter. The cylindrical element 22 is also made of a material with high X-ray absorption and makes it possible to simulate an aneurysm, which often has a neck of reduced diameter, simulated by the portion 24. The central shaft 14 also supports a ringed element 25 disposed obliquely relative to the central shaft 14 and provided with a succession of portions 26 of large diameter and portions 27 of small diameter, in order to make it possible to verify whether said portions 26 and 27 are displayed satisfactorily (refer to second portion coupled to a first portion and rotatable with respect to the first portion).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-5, 8, 16-18, are rejected under 35 U.S.C. 102(b) as being anticipated by Launay et al (U.S. patent 6,224,257).

Regarding claim 1, Launay discloses a phantom for use with an imaging device, comprising (column 3, lines 13-18, to simulate a rotating acquisition of images of the patient with a specific stimulation device also called "phantom").

a first portion including at least one group of vessel-like regions having a radiographically opaque quality, wherein the at least one group of vessel-like regions includes at least first and second vessel-like regions such that the first vessel-like region is larger than the second vessel-like region (column 2, lines 38-64, at least one image is acquired of a unit for simulating the patient's bones and soft tissue only, and at least one image is acquired of this unit and of the device for simulating the patient's opacified blood vessels, and using image subtraction, an image of the simulation device is obtained, also column 4, lines 8-22, provided with a succession of portions of large diameter and portion of small diameter, in order to make it possible to verify whether portions 26 and 27 are displayed satisfactorily);

and a second portion coupled to the first portion and rotatable with respect to the first portion, the second portion having a testing region of material radiographically similar to human tissue (column 1, lines 48-65, each wire can be disposed at a distance from the axis normal to the plane of rotation of the axis of the x-ray beam that is different from, also column 2, lines 38-64, at least one image is acquired of a unit for simulating the patient's bones and soft tissue and column 3, lines 13-18, in order to control the performance level of a three-dimensional angiography system, it is necessary to simulate a rotating acquisition of images of the patient with a specific simulated device called a "phantom", also column 4, lines 1-22).

Regarding claim 4, Launay discloses the phantom as recited in claim 1, wherein the testing region includes a first material radiographically similar to a first kind of human tissue and a second material radiographically similar to a second kind of human tissue (see claim 1, also column 2, lines 38-46, the patient's bones and soft tissue).

Regarding claim 8, Launay discloses the phantom as recited in claim 1, comprising an arm for rotating the first portion with respect to the second portion (column 3, lines 13-18, in order to control the performance level of a three-dimensional angiography system, it is necessary to simulate a rotating acquisition of images of the patient with a specific simulated device called a "phantom").

Regarding claim 17, Launay discloses the phantom as recited in claim 16, wherein the first kind of human tissue is bone tissue (column 2, lines 38-46, the patient's bones and soft tissue).

Regarding claim 18, Launay discloses the phantom as recited in claim 16, wherein the first kind of human tissue has a density greater than the second kind of human tissue (column 3, lines 19-33, the semi-circular elements 4 are made of a material with low X-ray absorption, for example polycarbonate, or another material of equivalent density. the simulation device comprises six semicircular elements 4 distributed uniformly in the circumferential direction. However, as a variant, it is possible to provide a different number, for example four or eight).

With regard to claims 3, 5 and 16, the arguments analogous to those presented above for claims 1, 4, 8 and 18 are respectively applicable to claims 3, 5 and 16.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 7 and 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Launay et al (U.S. patent 6,224,257) in view of White et al (U.S. patent 6,992,280).

However regarding claims 6 and 7, Launay does not explicitly state it's corresponding "wherein the radiographically opaque quality is a radio-opacity equivalent to iodine or barium. On the other hand White in the same field of x-ray and calibration of

image teaches (column 4, lines 48-59, X-ray contrast agent included barium or iodine compounds).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify, Launay invention according to the teaching of White because it containing compounds, which enhanced x-ray attenuation in the body zone into which they distribute for better accuracy in radiological imaging.

With regard to claim 19, the arguments analogous to those presented above for claims 6 and 7 are respectively applicable to claim 19.

Allowable Subject Matter

6. Claim 2 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable claims

7. Claims 9-15, 20-23 and 25-29 are allowable.

8. The following is an examiner's statement of reasons for allowance. Claim 9, representing claims 20 and 23, the closest prior art of record (Launay and White) does not teach or suggest, among other things, " at least one group of vessel-like regions has a level of a radiographically opaque quality; and a second portion coupleable to the first portion and having a first testing region and a second testing region arranged circumferentially with respect to one another, wherein [[each]] the first testing region includes a first attenuation material radiographically similar to a first type of human tissue and the second testing region includes a second attenuation material

radiographically similar to a second type of human tissue, the first testing region being configured to attenuate X-ray radiation more than the second testing region”.

The reason for allowance of claims 25-29, set forth in the previous office action dated on 6/22/2007 are not repeated herein, but are incorporated by reference. As applicants properly point out in the previous remark, the prior art (Launay and White) references fail to disclose the claimed limitations.

These key features in combination with other features of the claimed invention are neither taught nor suggested by the art of record.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Seyed Azarian
Patent Examiner
Group Art Unit 2624
December 1, 2007


SEYED AZARIAN
PRIMARY EXAMINER